UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,628	10/23/2003	Jacqueline J. Shan	2968-204	5928

6449 7590 03/13/2006

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
TATE, CHRISTOPHER ROBIN	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,628	SHAN ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2003 (preliminary amendment)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1003 & 0305*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 34-41 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is rendered vague and indefinite by the abbreviated term "CVT-E002" because this term, in and of itself, does not adequately define what this element represents in terms of its essential makeup (i.e., a ginseng fraction). This term, by itself, is also not consistent with the phraseology used to define the CVT-E002 in parent Application 09/581,161 (which issued as U.S. Patent No. 6,432,454). Accordingly, it is suggested that this term be expanded upon so as to recite --ginseng fraction CVT-E002-- to clearly define this element, as well as to be consistent with the parent claim language (of US '454).

In claims 35 and 37-40, the respective phrases "a low immunity condition effective treating amount of" (recited twice in clam 35), "a production stimulating effective amount of" (claim 37), "an *in vitro* and *in vivo* production stimulating amount of" (claim 38), "a B-lymphocyte proliferating amount of" (claim 39), and "a condition treating effective amount of" (claim 40) are unclear, awkward, and confusing. Further, since the therapeutic effects are already clear in the preambles of these claims (e.g., for treating low immunity, for stimulating

the production of IL-1, IL-6 and/or TNF-*a*, for stimulating the *in vitro* and *in vivo* production of immunoglobulins, for activating B-lymphocyte proliferation), these overall phrases are not deemed necessary. Accordingly, it is suggested that these phrases be omitted and replaced with --an effective amount of--.

Claims 38 and 39 are rendered vague and indefinite because it is unclear as to what/who the CVT-E002 is being administered to - e.g., is it being administered to a patient, to cells, to a flask, or something else?

Claim 39 recites the limitation "the resulting antibody production" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is suggested that this phrase be amended to recite --antibody production resulting from said B-lymphocyte proliferation--.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Double Patenting

Claim 34 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-9 of U.S. Patent No. 6,432,454. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a product comprising the ginseng fraction CVT-E002. The main differences are that the CVT-E-002 of US '454 is defined as a product-by-process or, alternatively, is defined by its overall carbohydrate content, and that the instant product of claim 34 further includes a pharmaceutically acceptable carrier. However, please note that the method by which the CVT-E002 is made or described does not distinguish the CVT-E002 product, per se. Further, it is

notoriously well known in the art to beneficially combine ginseng and ginseng extracts (including fractionated ginseng extracts) with a conventional pharmaceutical carrier so as to provide an efficient oral delivery form thereof since ginseng is an art-recognized medicinal herb, and extracts (including fractionated extracts) thereof are typically orally administered.

Please note that although the instant application is stated to be a Continuation Application of Application No. 10/188,733, which in turn is stated to be a Divisional Application of Application No. 09/581,161 (which issued as U.S. Patent No. 6,432,454), numerous claims within Application No. 09/581,161, including those drawn to ginseng fraction "CVT-E002" (e.g., original claim 25 in Application No. 09/581,161 - which issued as claim 7 in US '454) were rejoined in response to Applicants traversal presented in their 08 May 2001 response to the 11 April 2001 Restriction requirement. Accordingly, the above obviousness-type double patenting rejection is deemed proper.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1655